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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,075	09/22/2004	Raoul Donath	001227/0152	1247
69/095 7590 08/18/2009 STROOCK & STROOCK & LAVAN, LLP 180 MAIDEN LANE NEW YORK, NY 10038				
EXAMINER WOODALL, NICHOLAS W				
ART UNIT 3775		PAPER NUMBER		
MAIL DATE 08/18/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,075

Applicant(s)

DONATH, RAOUL

Examiner

Nicholas Woodall

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 9, 10 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9, 10 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the applicant's amendment filed April 29th, 2009.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4, 5, 9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) and in view of Katz (U.S. Patent 5,989,254).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end, and a first channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged orthogonal to the second channel. The set screw is threadingly engaged with the rear

end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection element and the inner surface of the sealing cap and the device further comprising a securing element. Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connection element to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter further comprising a securing element in view of Katz in order to restrain the connection element to the pedicle screw. As discussed above Schaffler-Wachter discloses a device comprising complementary arresting means in order to secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the sealing cap to the connection element. Because both Schaffler-Wachter and Gardner

teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

4. Claims 1, 2, 4, 5, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) and in view of Nichols (U.S. Patent 6,090,111).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end, and a first channel passing through the connection element transversely to the central

axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged orthogonal to the second channel. The set screw is threadingly engaged with the rear end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection element and the inner surface of the sealing cap and the device further comprising a securing element. Nichols teaches a device comprising a securing means that includes a snap-ring and groove configuration in order to retain the pedicle screw (column 4 lines 5-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter further comprising a securing element in view of Nichols in order to retain the pedicle screw. As discussed above Schaffler-Wachter discloses a device comprising complementary arresting means in order to

secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the sealing cap to the connection element. Because both Schaffler-Wachter and Gardner teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap of Schaffler-Wachter having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

5. Claims 15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918).

Schaffler-Wachter discloses a device comprising a connection element (6), a sealing cap (7), and a set screw (19). The connection element includes a central axis, an external surface, an upper end, a lower end, a first cavity extending coaxially along the central axis from the upper end to the lower end, wherein the first cavity further includes a shoulder having a level bearing surface of a circular shape at the lower end, and a first channel passing through the connection element transversely to the central axis for receiving the longitudinal carrier. The sealing cap includes a front end, a rear end, a second cavity opening at the front end to receive the connection element, and a second channel extending transversely to the central axis and opening towards the front end of the sealing cap and including an internal surface. The sealing cap further includes two slots (13) extending from the front end of the sealing cap and arranged orthogonal to the second channel. The set screw is threadingly engaged with the rear end of the sealing cap to secure the position of the longitudinal carrier inserted in the first channel. The external surface of the connection element and the internal surface of the sealing cap include complementary non-threaded arresting means (10 and 11) for securing the sealing cap to the connection element, wherein the arresting means includes orthogonal saw-tooth shaped bulges (10) extending continuously and non-threadingly around the central axis of the connection element on the internal surface of the sealing cap. Schaffler-Wachter fails to disclose the device further comprising an arresting means that includes a plurality of complementary bulges and depressions concentrically located on the external surface of the connection. As discussed above Schaffler-Wachter discloses a device comprising complementary arresting means in

order to secure the sealing cap to the connection element. Gardner teaches a device comprising a sealing cap, a connection element, and complementary arresting means including a plurality of axially displaced orthogonal saw-tooth shaped bulges and recesses located on the external surface of the connection element and the internal surface of the sealing cap in order to secure the sealing cap to the connection element. Because both Schaffler-Wachter and Gardner teach devices comprising complementary arresting means between a sealing cap and a connection element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one complementary arresting means for the other in order to achieve the predictable results of securing the sealing cap to a connection element. The device of Schaffler-Wachter as modified by Gardner disclose a device wherein the complementary arresting means are capable of allowing the sealing cap to being positioned at a first position, wherein a first set of bulges are engage with a first set of recesses, and moveable to a second position, wherein the first set of bulges and a second set of bulges are engaged with the first set of recesses and a second set of recesses, wherein the sealing cap is axially displaced along the connection element.

Regarding the complementary arresting means being concentrically located along the surfaces of the connection element and the sealing cap, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the connection element and the sealing cap of Schaffler-Wachter having a circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person

ordinary skill in the art would find obvious for the purpose of providing a sealing cap or a connection element. In re Dailey and Eilers, 149 USPQ 47 (1966).

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffler-Wachter (U.S. Publication 2001/0012937) in view of Gardner (U.S. Patent 2,877,918) further in view of Katz (U.S. Patent 5,989,254).

The device of Schaffler-Wachter as modified by Gardner discloses the invention as claimed except for the device further comprising a securing element. Katz teaches a device comprising a securing means that includes a pin and hole configuration in order to restrain the connection element to the pedicle screw (column 2 lines 61-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Schaffler-Wachter as modified by Gardner further comprising a securing element in view of Katz in order to restrain the connection element to the pedicle screw.

Response to Arguments

7. Applicant's arguments filed April 29th, 2009 have been fully considered but they are not persuasive. The applicant's argument that the Gardner reference is non-analogous art is not persuasive. First, the examiner would like to note that the MPEP states, "The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." KSR International Co. v. Teleflex Inc., 550 U.S. ___,

_____, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." (See MPEP 2141.01(a)). The subject matter at issue is the connection between the cap and an element inserted into the cap in both the Schaffler-Wachter reference and the Gardner reference. The Schaffler-Wachter reference shows a cap connected to an inner member, wherein the connection includes arresting means comprising a single set of saw-tooth shaped bulges that engage the inner member of the device. The Gardner reference shows a cap connected to a bottle neck, i.e. an inner member, wherein the connecting includes complementary arresting means comprising a plurality of axially displaced orthogonal saw-tooth shaped bulges and recess located on the surfaces of the cap and the bottle neck. Because both references disclose devices comprising a connection between a cap and a member inserted within the cap, it would have been obvious to substitute the connection of the Schaffler-Wachter reference with the connection of the Gardner reference to achieve the predictable results of connecting the cap to the member inserted into the cap. Since the subject matter at issue is the connection between the cap and the element inserted into the cap, the Gardner reference is clearly analogous to the Schaffler-Wachter reference for the purpose of teaching a type of connection between a cap and an element inserted into the cap. The applicant's argument that the examiner did not provide a reason why a person of ordinary skill in the art would modify the device disclosed in the Schaffler-Wachter reference with the teachings of the

Gardner reference is not persuasive. The examiner provided the motivation to modify the Schaffler-Wachter by substituting the connection, i.e. the arresting means, between the cap and the member inserted into the cap with the connection, i.e. the arresting means, taught by Gardner in order to secure the sealing cap to the connection element, i.e. the member inserted into the cap (for example see page 3 lines 17-21 and page 4 lines 1-6). The applicant's argument that the examiner used hindsight is not persuasive. The examiner would like to note that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). The applicant's argument that the Gardner reference teaches away from the combination is not persuasive. The applicant provides example of how the cap from the Gardner reference could not be used with the Schaffler-Wachter system without destroying the cap, but these examples are moot. The examiner is not substituting the cap of Schaffler-Wachter with the cap taught by Gardner. The examiner is substituting the connection between the cap and the member inserted into the cap of Schaffler-Wachter with the connection between the cap and the member inserted into the cap taught by Gardner. Therefore, all the proposed modification is doing is replacing the bulge at the bottom of the Schaffler-Wachter cap with a plurality of axially spaced bulges and recesses as taught by the Gardner reference in order to connect the cap to the member inserted into the cap. The

applicant also states that the Gardner cap is made from a plastic material not suitable for the body. As discussed above, the examiner is not substituting on cap for the other cap. Therefore, the cap of the Schaffler-Wachter reference is still present including the material the cap is made from. The only modification is the substitution of the connection between the cap and the member inserted into the cap as disclosed by Schaffler-Wachter with the connection between the cap and the member inserted into the cap as taught by the Gardner reference. The applicant has not amended the claims and the examiner has not provided any new grounds of rejections making this office action **FINAL**.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775